510(k) SUMMARY

The following 510(k) summary is being submitted as required by 21 CFR 807.92(a):

1. **Submitter:** L&K BIOMED Co., Ltd.
#1104, Ace High-end Tower 3 cha, 371-50,
Gasan-Dong, Geumcheon-gu, Seoul 153-803
Republic of Korea
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Contact Person: Hee Kyeong Joo
E-mail.hkjoo83@gmail.com

Date prepared: September 7, 2011

2. **Device Identification**

Proprietary Name	FOCUS Spinal System
Common Name	Pedicle Screw Spinal System
Product Code	MNI,MNH, NKB
Classification Name	Pedicle Screw Spinal System (888.3070)

3. **Predicate or legally marketed devices which are substantially equivalent**
- **L&K BIOMED**: VENUS BASIC Spinal Fixation System (K100706, K103085)
- **STRYKER SPINE**: MANTIS™ Spinal System (K061813)
- **DEPUY SPINE**: Expedium ™ MIS Spine System (K041801,K090648)

4. **Description of the Device**
FOCUS Spinal System consists of cannulated polyscrews, straight rods, curved rods, crosslinks and set screw components that can be used via percutaneous surgical approach. The components are available in a variety of diameters and lengths in order to accommodate patient anatomy and are fabricated from titanium alloy (ASTM F136). The implants will be provided non-sterile.

5. **Intended use**

The FOCUS Spinal System is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of acute and chronic instabilities or deformities of the thoracic, lumbar and sacral spine. And the FOCUS Spinal System can be used in an open approach and a percutaneous approach with MIS instrumentation.

The FOCUS Spinal System is intended for noncervical pedicle fixation and nonpedicle fixation for the following indications: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e., fracture or dislocation); spinal stenosis; curvatures (i.e., scoliosis, kyphosis, and for lordosis); tumor; pseudarthrosis; and failed previous fusion in skeletally mature patients.

When used in a percutaneous approach with MIS Instrumentation, the FOCUS Spinal Systems are intended for noncervical pedicle fixation and nonpedicle fixation for the following indications: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e., fracture or dislocation); spinal stenosis; curvatures (i.e., scoliosis, kyphosis, and for lordosis); tumor; pseudoarthrosis; and failed previous fusion in skeletally mature patients.

6. **Comparison of the technology characteristics of the device to predicate and legally marketed devices**

There are no significant differences between the FOCUS Spinal System and other systems currently being marketed which would adversely affect the use of the product. It is substantially equivalent to these other devices in design, function and intended use.

7. **Performance Data**

Static compression bending, tension, torsion and dynamic compression bending were performed according to ASTM F1717 on a worst-case, screw construct. The mechanical test results demonstrated that the FOCUS Spinal System performs as well as the predicate device.

8. **Conclusion**

The FOCUS Spinal System is substantially equivalent to the devices referenced above and is therefore safe and effective for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

L & K Biomed Co., Ltd.
% Ms. Hee Kyeong Joo
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Seoul, Republic of Korea 153-803

JAN - 4 2012

Re: K112643
Trade/Device Name: FOCUS Spinal System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class III
Product Code: NKB, MNH, MNI
Dated: March 17, 2011
Received: December 05, 2011

Dear Ms. Joo:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

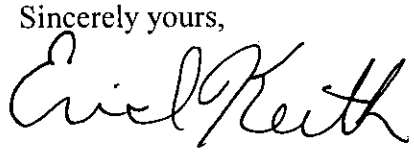
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



for Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

L&K BIOMED

Indications for Use Statement

510(k) Number (if known): K112643

Device Name: FOCUS Spinal System

Indications For Use:

The FOCUS Spinal System is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of acute and chronic instabilities or deformities of the thoracic, lumbar and sacral spine. And the FOCUS Spinal System can be used in an open approach and a percutaneous approach with MIS instrumentation.

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Prescription Use √ AND/OR Over-The-Counter Use _

(Part 21 CER801 Subpart D) (21 CER801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Stephen Gotzold

(Division Sign-Off) Concurrence of CDRH, Office of Device Evaluation (OED)

Division of Surgical, Orthopedic, and Restorative Devices

510(k) Number K112643